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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,739	11/23/2001	Dosuk D. Lee	112430.134US7	1714

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CLARK & ELBING LLP
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BOSTON, MA 02110

EXAMINER

LEVY, NEIL S

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 10/11/03
☐ This action is FINAL.

☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 18-31 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 18-31 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

Examiner appreciates references, those submitted by applicant, undated pre priority date, thus, prior art of this application.

"Fig. 4B" needs to be inserted on p.3/19. Insert also, A & B, on p. 14/19.

Claims 18-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over constantz et al 582062 in view of Niwa 4429691 and Sugihara et al WO 9000892, further in view of Sampata et al '92 and Glowacki et al 4440750.

The rejection of record is maintained, with the added elucidation. Although, as applicant argues, there is no demineralized bone specified in the primary reference, the prior art, sampata shows it is well known and old, and here utilized shows it to favor induction of osteogenic activity when implanted (p.140).

Therefore inclusion of this demineralized bone powder with the materials cited by constants, inclusive of osteogenic factors- col.6, would be an obvious element to enhance bone repair. In particular, the collagen matrix left after demineralization is in fact generally included in constants recitation of collagen (col.6, last line). Glowacki also shows (col.3, lines 5-6) osteogenic activity, when demineralized bone with collagen are injected in a fluid carrier at a desired site of bone defect (col.4, lines 24-41). Applicants show no criticality of the demineralized bone over any other of the supplementary materials (instant p.37, lines 23-26) inclusive of collagen chitin, keratin, as shown by constantly.

At the time of the instant invention, the artisan would find it obvious to prepare particular ingredient combinations, concentrations and ratios of ingredients, depending upon the disease syndrome, nutritional status, dietary Ca, P, content and form of the

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bone defect condition to be repaired, and thus include in the constantz model, the claimed components, the demineralized bone shown to enhance osteogenic activity.

The selection of active ingredients and concentrations are result effective parameters chosen to obtain the desired effects. It would be obvious to vary concentration and form to each ingredient to optimize the effect desired, and the use of ingredient for the functionality for which they are known to be used is not a basis for patentability.

It has not clearly been established by objective showing of unobvious and/or unexpected results, that the administration of the particular form of active, carrier, or the particular form of structure to be treated provides any greater level of prior art expectation as claimed. Further applicants rely on citing of the demineralized references to shows advantages applicant claims are attributable to the demineralized bone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday- Friday 7:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.



NEIL S. LEVY
PRIMARY EXAMINER